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PATENT SPECIFICATION

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(54) ENDOCARDIAC ELECTRODE DEVICES

(71) I, HANS RAGNAR LAGERGREN, a Swedish citizen, of Östermalmsgatan 89, S-11459 Stockholm, Sweden, do hereby declare the invention, for which I pray that a patent may be granted to me, and the method by which it is to be performed, to be particularly described in and by the following statement:—

The invention relates to endocardiac electrode devices, for example a device for intracardial stimulation of the heart, consisting of an elongate electrical conductor which is provided with electrical insulation, and an electrode head, provided at that end of the conductor which is closer to the heart when the device is in use (the proximal end), for applying stimulating pulses to the heart when the electrode is introduced. The electrode head may be metallic and may be small and light relative to the size and weight of the conductor itself. However, it may as a result be difficult to locate the head on a sufficiently stimulation-sensitive part of the myocardium, and there may be a danger that the electrode head is shifted by movements of the heart owing to its small mass so as to be positioned on a point of the endocardium/myocardium where the energy content of a stimulating pulse is insufficient to stimulate the heart.

According to the present invention there is provided an endocardiac electrode device for intracardially stimulating the heart, comprising an elongate electrically conductive member insulated by a sheath of electrically insulative material, and a head portion at a proximal end of the conductive member, the head portion being of relatively massive construction as compared with the insulated conductive member and having lateral surface regions of electrically insulative material between lateral surface regions, distributed substantially uniformly over the surface of the head portion, of electrically conductive material which is in electrical connection with the said elongate electrically conductive member.

An embodiment of the present invention can be made in which the aforementioned difficulty and danger are reduced in degree, and which nevertheless can be operated with stimulating pulses of low energy content in relation to that normally required for such pulses. The electrode head portion is large, relative to the size of the elongate electrically conductive member, while having a small conductive contact area with the endocardium/myocardium, and is of high weight relative to that of the elongate electrically conductive member, while being capable of being positioned for use and withdrawn without any problem. The surface of the conductive contact material may be so dimensioned as to be substantially equal to the surface area of the smallest known electrode heads. In this way, the current density produced on the conductive contact surface regions may be correspondingly high.

The contribution made, to the total surface area of the electrode head, by insulating material results in the head portion being made larger and heavier, in relation to a head portion without insulating material, so that it can be more readily and reliably positioned on the endocardium/myocardium and can remain more securely positioned on the endocardium/myocardium despite movements of the heart. The conductive contact material is distributed laterally and substantially uniformly over the whole surface of the electrode head portion, so that, in positioning the head portion on the endocardium/myocardium, there is a greater probability that conductive contact regions of the electrode head portion will be located on a particularly stimulation-sensitive part of the myocardium. The exposed surface area of the conductive contact material of the electrode head portion is preferably not larger than 15 mm^2, and is preferably 5 mm^2. The exposed surface of the conductive contact material of the electrode head portion may be arranged in strip form (for example in spiral

form), or dot-like. The electrode head portion may have a volume in the range from substantially 15 mm^3 to substantially 60 mm^3, preferably substantially equal to 25 mm^3, while the weight may be in the range from substantially 0.30 g to substantially 2.0 g, preferably 0.8 g. With such a construction of the electrode head portion, it can be of substantially cylindrical form, while its free end may be rounded. The conductive contact material may consist of strip material. The width of the strip may be between about 0.01 mm and 0.4 mm, and is preferably 0.2 mm. The strip may be disposed on the cylindrical electrode head portion in the form of webs extending in parallel relationship is the direction of the axis thereof. The distance between adjacent webs can be in the range from substantially 0.5 mm to substantially 5 mm, preferably 1.5 mm. Alternatively the strip may be in spiral form. In this case, the distance between the turns of the spiral may be in the range from 0.5 mm to 5 mm, and is preferably 2mm. The spiral may be formed by a strip wrapped helically around the cylindrical portion of the electrode head portion. The weight of the electrode head portion can readily be made greater than the weights mentioned hereinbefore (whereby a reliable positioning in the right-hand ventricle of the heart can be achieved).

Manufacture can be simplified by making the electrode head portion of an electrically conductive metallic core having protruding portions of electrically conductive material, the interspace between the protruding portions being filled with electrical insulating material. The protruding portions may be made in the form of ribs, in the form of a screwthread, or in hedgehog form or the like in order that the stripform, spiral or dot-like arrangement of the exposed surface of conductive contact material on the electrode head portion may be obtained. With this form of construction, the free end of the elongate conductor of the endocardiac electrode device can be particularly easily connected to the electrode head portion. The electrically conductive head would, of course, be in electrical connection with the elongate electrically conductive member of the device.

The electrode head portion may alternatively consist substantially entirely, or partially, of insulating material, preferably of ceramic material or the like, in which case the conductive contact surface regions of the electrode head portion can be applied by evaporation or electrodepostion. Alternatively, the contact regions may be formed from a cage-like wire lattice which is at least partially filled with insulating material.

The conductive contact material of the electrode head portion may be connected to the elongate electrically conductive member by spot welding or soldering; alternatively, the connection may be made by means of a conductive bonding agent.

Reference will now be made, by way of example, to the accompanying diagrammatic drawing, in which Figures 1 to 3 show respective axial part-sectional views of devices embodying the present invention.

Each of the Figures shows the distal end, with respect to a pacemaker, of an endocardiac electrode device.

In the Figures, like parts are labelled with the same reference numeral.

In Figure 1, there is denoted by 1 an elongate electrical conductor of an electrode device, which conductor is insulated by a sheath of electrical insulation 2. Situated at the proximal end of the electrode device is an electrode head 3, which is of substantially cylindrical form and is rounded at its free end. The surface of the said electrode head consists partly of electrically insulating material 4 compatible with the human body and partly of electrically conducting contact material 5. In Figures 1 and 2, the contact material lying on the surface of the electrode head is of strip-form. In the case of Figure 1 the contact material is disposed on the substantially cylindrical electrode head in the form of webs extending in parallel relationship to the axis of the head. In the case of Figure 2, the contact surface extends helically around the substantially cylindrical portion of the electrode head. In the illustrated Figures, the total length of the electrode head in the direction of its axis is 6 mm and its diameter is 3 mm. The total area of the contact material is 5 mm^2.

In Figure 3, the contact surface regions of the electrode head are dot-like and are distributed over the whole area of the electrode head.

In each embodiment of the present invention shown in Figures 1 to 3, the electrically conducting contact material 5 is in electrical connection with the elongate electrical conductor 1.

In this paragraph, the numerical values indicate the range of the specific gravities, in g per cubic cm, of the solid insulating materials and plastics, which may be used for the electrically insulating material 4 of the illustrated embodiments, following those numerical values: 0.5—0.9; insulating paper; 0.9—1.0: polyethylene, polybutene, polypropylene, unfilled rubber, polyisobutylene; 1.0—1.2: polystyrene, normally filled soft and hard rubber,

cellulose ether, polymethacrylates, polycarbonate, unfilled polyester and epoxy resins; 1.2—1.4; vulcanised fibre, cellulose ester, polyvinyl ester, including hard and soft PVC, phenolic resins, phenolic resin moulding compounds having organic compounds with organic fillers, acetal resins; 1.5—1.8; polyvinylidene chloride, rubber chloride, moulding compounds having inorganic fillers, reinforced plastics, indurated fabric; 1.8—2.3; silicones, polytetrafluoroethylene and other fluorine-containing polymers; 2.2; quartz glass; 2.3—2.5; hard porcelain; 2.6—2.8; steatites; 2.8; mica; 2.2—3.8; technical glasses; 3.1—3.9; ceramic insulating materials containing titanium oxide. Thus the specific gravity of the electrically insulating material 4 can be in the range from 0.5 to 3.9 g per c.c.

It will be appreciated from Figures 1 to 3 that, in each case, the axis of the cylindrical electrode head 3 is parallel to the elongate electrical conductor 1. It will also be appreciated, from the dimensions and specific gravities given hereinbefore, that the electrode head 3 of each of the illustrated devices is of relatively massive construction as compared with the insulated conductor 1.

WHAT I CLAIM IS:—

1. An endocardiac electrode device for intracardially stimulating the heart, comprising an elongate electrically conductive member insulated by a sheath of electrically insulative material, and a head portion at a proximal end of the conductive member, the head portion being of relatively massive construction as compared with the insulated conductive member and having lateral surface regions of electrically insulative material between lateral surface regions, distributed substantially uniformly over the surface of the head portion, of electrically conductive material which is in electrical connection with the said elongate electrically conductive member.

2. A device as claimed in claim 1, wherein the total surface area of all the surface regions of electrically conductive material of the head portion is not more than 15 mm^2.

3. A device as claimed in claim 2 wherein the said total surface area is 5 mm^2.

4. A device as claimed in claim 1, 2 or 3, wherein the said head portion has a volume in the range from substantially 15 mm^3 to substantially 60 mm^3, and has a weight in the range from substantially 0.30 g to substantially 2.0 g.

5. A device as claimed in claim 4, wherein the said head portion has a volume substantially equal to 25 mm^3.

6. A device as claimed in claim 4 or 5, wherein the said head portion has a weight substantially equal to 0.8 g.

7. A device as claimed in any preceding claim, wherein the said head portion is of substantially cylindrical form having an axis extending substantially parallel to a longitudinal axis of the said elongate electrically conductive member, the said head portion being rounded at its free end.

8. A device as claimed in any preceding claim, wherein the said surface regions of electrically conductive material are dot-like.

9. A device as claimed in any one of claims 1 to 7, wherein the said surface regions of electrically conductive material are in strip form.

10. A device as claimed in claim 9, wherein the said electrically conductive material is also in strip form.

11. A device as claimed in claim 9 or 10, wherein the width of the strip or strips is in the range from substantially 0.01 mm to substantially 0.4 mm.

12. A device as claimed in claim 11, wherein the width of the strip or strips is substantially equal to 0.2 mm.

13. A device as claimed in any one of claims 9 to 12, wherein the said surface regions of electrically conductive material are parts of a spiral.

14. A device as claimed in claim 13, wherein successive turns of the spiral are separated by a distance in the range from substantially 0.5 mm to substantially 5 mm.

15. A device as claimed in claim 14, wherein the said distance is substantially equal to 2 mm.

16. A device as claimed in any one of claims 13 to 15, when read as being appended to claim 7, wherein the said spiral is in the form of a helix extending along the head portion.

17. A device as claimed in any one of claims 9 to 12, wherein the said surface regions of electrically conductive material consist of a plurality of strips which extend parallel to one another.

18. A device as claimed in claim 17, when read as being appended to claim 7, wherein the said plurality of strips extend substantially parallel to the said axis.

19. A device as claimed in claim 18, wherein the distance between adjacent strips is in the range from substantially 0.5 mm to substantially 5 mm.

20. A device as claimed in claim 19, wherein the distance mentioned in claim 19 is substantially equal to 1.5 mm.

21. A device as claimed in any one of claims 1 to 9, or as claimed in any one of claims 11 to 20 except when read as being

appended to claim 10, wherein the said head portion comprises a core of electrically conductive material in electrical connection with the said elongate electrically conductive member, from which core extend portions of electrically conductive material which provide the said surface regions of electrically conductive material, the interspace between the portions which extend from the said core being filled with electrically insulative material which provides the said surface regions of electrically insulative material.

22. A device as claimed in any one of claims 1 to 7, wherein the head portion consists of a wire lattice cage which provides the said surface regions of electrically conductive material, there being electrically insulative material within the said cage, which electrically insulative material provides the said surface regions of electrically insulative material.

23. A device as claimed in any preceding claim, wherein the electrically insulative material of the head portion has a specific gravity, in the range from substantially 0.5 g per cc. to substantially 3.9 g per cc.

24. An endocardiac electrode device for intracardially stimulating the heart, substantially as hereinbefore described with reference to Figure 1, 2 or 3 of the accompanying drawing.

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1 SHEET *This drawing is a reproduction of the Original on a reduced scale*

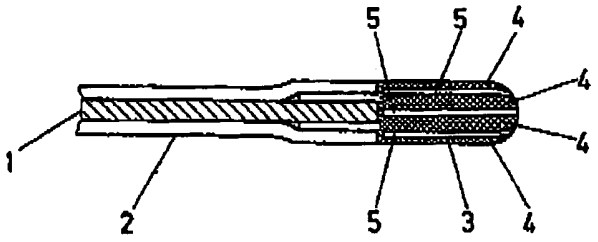

Fig. 1

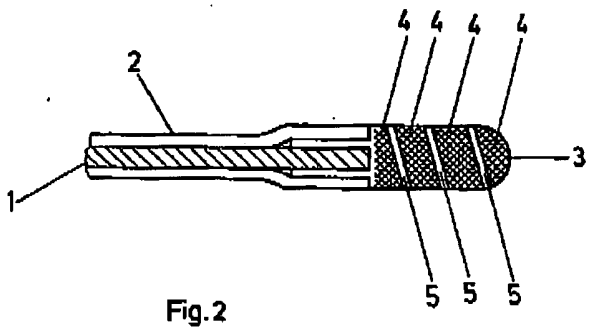

Fig. 2

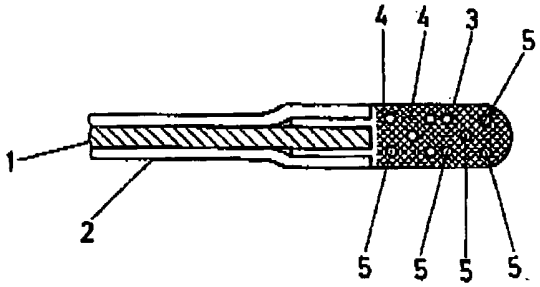

Fig. 3